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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
CLARK, AMY LYNN				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/549,740

Applicant(s)

LAGUNA GRANJA ET AL.

Examiner

Amy L. Clark

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 26-37 is/are pending in the application.
- 4a) Of the above claim(s) 26-30 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 31 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ ~~Copies of the certified copies of the priority documents have been received in this National Stage~~
application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 05/23/2011 with the newly added claims 35-37.

Election/Restrictions

The election/restriction requirement is maintained for reasons of record.

Any rejection found in the previous Office Action and not repeated herein has been withdrawn based upon Applicant's amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14, 15, 31 and 33-37 are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention (newly applied as necessitated by amendment).

In newly added claim 35, Applicant claims, “a lipid fraction” in lines 1 and 2, which does not appear to have support in the originally filed specification and is deemed to be new matter. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited phrase “lipid fraction” which would show possession of this concept. The specification discloses a lipid extract; however, this is not the same as a lipid fraction. A lipid extract is an extract that contains lipids or is itself a lipid and is distinct both by definition and by practice/method steps from a lipid fraction, which requires additional steps to fractionate a lipid from an extract (including, but not limited to, column chromatography and/or solvent partitioning). There does not appear to be any mention of fractioning the lipid to provide a lipid fraction in the originally filed specification and, thus, there is not sufficient support for a “lipid fraction”. This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted

from the claim language, unless Applicant can particularly point to the specification for literal support.

Claim 14 remains rejected under 35 U.S.C. 102(b) as anticipated by El-Khalaty et al. (Applicants' IDS NPL Reference 4*).

El-Khalaty teaches an oil fraction obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds (which reads on fruit, since the royal palm seed contains the fruit) comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% (See table IV, page 273), which read on the ranges of each fatty acid component of Applicants' pharmaceutical composition in claim 15. El-Khalaty further teaches that the oil is obtained through a process of first crushing the seed, then defatting the seed followed by subjecting the resulting seed meal to acidic and alkaline hydrolysis (See page 270).

Although El-Khalary does not expressly teach that the oil fraction is a pharmaceutical, the claimed functional properties are inherent to the preparation taught by El-Khalary because El-Khalary expressly teaches the same composition taught by Applicants based upon the fatty acid profile provided by El-Khalary and the method taught by El-Khalary of obtaining the fatty acid profile from the seeds of royal palm. Thus, a pharmaceutical composition is inherent to the oil fraction composition taught by El-Khalary.

Therefore, the reference anticipates the claimed subject matter.

Claims 14, 15, 31, 33 and 34 remain rejected and newly added claims 35-37 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Rabarisoa et al. (X*, Translation provided with the previous Office Action) (partially newly applied as necessitated by amendment).

Rabarisoa teaches an extract of *Oreodoxa regia* (which is synonymous with *Roystonea regia*) fruit (See pages 5 and 6, Extract number 15) with the same fatty acid profile claimed by Applicant (see Table III, number 15). Rabarisoa further teaches that the triglycerides were transformed into methyl esters using methanol (which reads on ester hydrolysis) (See page 3) after extraction with hexane (which also reads on the limitations of claims 33 and 34, since combining *Roystonea regia* fruit with hexane would result in only *Roystonea* whole fruit and a liquid extract, since the hexane would provide a *Roystonea regia* extract and would inherently contain the fatty acids with the instantly claimed profile) (please note that the extract of *Roystonea regia* inherently contains a lipid fraction with the profile claimed by Applicants and the extract of *Roystonea regia* itself reads on a composition).

Although Rabarisoa does not expressly teach that the oil fraction is a pharmaceutical or that the fruit is expressly green or mature, the claimed functional properties are inherent to the preparation taught by Rabarisoa because Rabarisoa expressly teaches the same composition taught by Applicants based upon the fatty acid profile provided by Rabarisoa and the method taught by Rabarisoa of obtaining the fatty acid profile from the fruit of royal palm. Thus, a pharmaceutical composition is inherent to the oil fraction composition taught by Rabarisoa.

Therefore, the reference anticipates the claimed subject matter.

Response to Arguments

Applicants' arguments concerning the 35 U.S.C. § 102(b) under El-Khalaty rejection above have been thoroughly considered but are not deemed persuasive of error in the rejection.

Applicants argue that El-Khalaty et al. is directed to food seed oil and that the profile of fatty acids taught by El-Khalaty is different than that claimed by Applicants. Applicants further argues that El-Khalaty teaches separating the seeds from the epicarp and therefore teaches away from the whole fruit and the present invention and that "kernel oil" is very different from the "palm oil" obtained from pericarp of the fruit (Exhibit A).

However, this is not found persuasive because according to "Everyday mysteries: Fun Science Facts from the Library of Congress" (Reference V*), botanically speaking, a coconut is a fibrous one-seeded droupe, also known as a dry drupe, but that when using loose definitions, the coconut can be a fruit, a nut and a seed. "The Free Dictionary: palm" (Reference W) teaches that the seed size of the palm varies, as does the trunk height and diameter and the leaf length and that the fruits of palms, covered with a tough fleshy, fibrous, or leathery outer layer, usually contain a large amount of endosperm in the seed (stored food) (please note that "Everyday mysteries: Fun Science Facts from the Library of Congress" teaches Some scientists like to refer to the coconut as a water dispersal fruit and seed and that that in addition to the "baby" plant in the seed, there is the food to kick off its life called the endosperm. The endosperm is what makes up most of the seed and, in the coconut's case, is the yummy white stuff we eat, which reads on fruit). "The Free Dictionary: palm oil" teaches that palm oil is the fat pressed from the fibrous flesh of the fruit of many palms. Therefore, it is understood in the art that "seed" can be used interchangeably to mean the fruit of the palm. El-Khalaty also uses this term loosely throughout

the introduction, for example EI-Khalaty teaches that "the characteristics and fatty acid composition of the *Oreodexa regia* (royal palm) oil from a lot of nuts from Cuba were studied by Stillman et al, and the constants of the oil were fat content (of the kernel)...the fatty acid composition of the oil was..." which demonstrates a difference between the seed as a whole (which contains the fruity pulp of the royal palm) and the kernel. EI-Khalaty further teaches that seeds and kernels were investigated in the extraction of oil (See page 270). Finally, Stillman (Reference U*, prior art of record) teaches that the nut of the Cuban palm contains 25% oil and that upon further examination, the ripe fruit of the Cuban palm contains the same oil as that obtained from the kernel of the Cuban palm (again, demonstrating that "seed" contains fruit) and describes saponifying the oil and fractioning the oil to obtain a fatty acid profile. Therefore, it would be expected that at the very least the fatty acid profile of the fruit and of the seed (if there is indeed a difference) would be the same or similar between the oil obtained from the kernel and the fruit and the profile of the whole of the seed would be expected to be consistent with the profile of oil obtained from the fruit and the profile of the oil obtained from the kernel. Therefore, EI-Khalaty reads at least on a mixture of primary fatty acids with 8 to 28 carbon atoms obtained from ripe fruit of *Roystonea regia* (synonymous with Cuban palm and Cuban palmiche), and at the very least anticipates the subject matter of claim 14, which does not recite exact amounts of each fatty acid and does not require that all of the fatty acids in the claim be present in the composition. Further, the method of obtaining the extract from EI-Khalaty appears to be identical to the process, as claimed, by which Applicants have obtained their extract of the Cuban palm fruit and would be expected to contain a similar profile. Optimizing one particular fatty acid would have been obvious to one of ordinary skill in the art (as set forth above and in

the previous Office Action).

As currently drafted, claim 14 remains rejected for the reasons of record and for the reasons set forth above.

Applicants' arguments concerning the 35 U.S.C. § 102(b) under Rabarisoa rejection above have been thoroughly considered but are not deemed persuasive of error in the rejection.

Applicants argue that Rabarisoa discusses different species and different parts of the fruits that provide different results. Applicants further argue that the fatty acid profile of the pericarp is distinct from the fatty acid profile of the kernel. Applicants further argue that *Roystonea regia* fruit is different than *Cocos nucifera* fruit.

However, this is not found persuasive because Rabarisoa teaches an extract of *Oreodoxa regia* (which is synonymous with *Roystonea regia*) fruit with the same fatty acid profile claimed by Applicants. Further, it should be noted that pericarps are regarded as whole fruit of a plant and reads on whole fruit, particularly since Applicants' originally filed specification does not provide a definition of the term "whole fruit" nor actually mention the term "whole fruit". Therefore, given the term's broadest reasonable interpretation, pericarp (which is the entire flesh of a fruit- see the accompanying dictionary definition, Reference U1 and definition of fruit, reference V1) is synonymous with "whole fruit" and therefore, the fruit taught by Rabarisoa, which has the same fatty acid profile as claimed by Applicants, is considered to be the same as that claimed by Applicants, particularly since Applicants have not demonstrated that there is a difference between the fruit claimed by Applicants and that taught by Rabarisoa. Therefore, the rejection is maintained for the reasons of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/
Primary Examiner, Art Unit 1655